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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/832,497 | 04/11/2001 | Robert S. Behl | 16807001530 | 1252 |
| 23639 | 7590 | 01/30/2004 | | |
| BINGHAM, MCCUTCHEN LLP THREE EMBARCADERO, SUITE 1800 SAN FRANCISCO, CA 94111-4067 | | | EXAMINER VRETTAKOS, PETER J | |
| | | | ART UNIT 3739 | PAPER NUMBER 20 |
| DATE MAILED: 01/30/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

5

Office Action Summary

Application No.

09/832,497

Applicant(s)

BEHL ET AL.

Examiner

Peter J Vrettakos

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-34, 36, 39-41, 44, 46, 51 and 65-93 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32-34, 36, 39-41, 44 and 46 is/are allowed.
- 6) ☒ Claim(s) 66-93 is/are rejected.
- 7) ☒ Claim(s) 51 and 65 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Art Unit: 3739

DETAILED ACTION

The instant action is non-final.

Claims 32-34,36, 39-41,44,46,51, and 65-93 are pending.

Claims 1-31, 35, 37, 38, 42-43, 45, 47-50, and 52-64 are cancelled.

Claims 65-93 are newly added.

Claims 32-34, 36,39-41,44, and 46 are allowed.

Castro is presented in the rejections below. The patent was initially cited as art of interest in the Office Action dated 8-20-03.

Claim Objections

Claims 51 and 65 are objected to because of the following informalities: **Claims 51 and 65 depend upon a cancelled claim.** Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 66-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over LeVeen in view of Castro.

Independent claims 66, 73, 80, 87 and dependent claims 81, 88

LeVeen et al. (**LeVeen**) discloses a system for treating a target region beneath a tissue surface, said system comprising (see figures 11-14):

a probe (510) having a distal end adapted to be positioned beneath the tissue surface to a site in the tissue;

a plurality of electrodes (520) deployable from the distal end of the probe to span a region of tissue proximate the target region; and

a cover (**the disc** at the proximal end of sheath 502) removably or selectably attachable to the probe and adapted to span a region of tissue over the target region.

Castro discloses an obturator (12; analogous to LeVeen 502) and a cannula (20; analogous to 510/516) capable of being **locked** together by a connecting mechanism (47). From this, it would be obvious to include a connector between LeVeen's 502 and 510.

Re: claim 87, Castro discloses a member (22, see figure 3) attachable to the probe having a cover (distal wall of 22) adapted for placement on the tissue surface without any portion of the member (22) penetrating beneath the tissue surface.

Dependent claims

Art Unit: 3739

Re: claims 67, 74, 82, and 90, LeVeen depicts in fig. 11 a cover (502, disc) with a flat face.

Re: claims 70, 77, 85, and 92, LeVeen discloses a probe comprising a cannula (515) having a proximal end, a distal end, and wherein the plurality of electrodes (520) are disposed in the cannula lumen to reciprocate between a proximally retracted position wherein all electrodes are radially constrained within the lumen and a distally extended position wherein all electrodes deploy radially and everted outwardly (fig. 14).

Re: claims 68, 71, 72, 75, 78, 79, 83, 86, and 91, LeVeen neglects to expressly disclose cover, cannula, or electrode dimensions.

However, the Examiner contends that one of ordinary skill in the art would have ascertained the optimal values (assuming that the parameters in the Applicant's claims are optimal) for these parameters via routine experimentation. The motivation to acquire these parameters would be to develop a superior protocol.

Re: claim 88, it would have been obvious that to address the individual medical application of the device to create a connector in the LeVeen – Castro hybrid device that would permit selective attachment of the member (22) to the probe (20 in Castro; 510 in LeVeen) at different axial positions along the probe.

Re: claims 69, 76, 84, and 92, LeVeen discloses in column 1:62-65 that in RF hyperthermia treatment, conventionally a needle (analogous to electrode) is

Art Unit: 3739

- partially sheathed in plastic. This can be inferred as saying that the sheath (502) in LeVeen, which includes the cover/disc is plastic and therefore, electrically and thermally insulative. This would make sense, because the goal of RF treatment as disclosed in LeVeen is to apply electricity/heat to targeted tissue beneath a surface and not to the surface itself. Making the sheath and cover/disc out of plastic or another electrically and thermally insulative material would avoid unwanted surface heating.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify LeVeen in view of Castro by including a connecting mechanism between a probe and a cover adapted for placement on the tissue surface over the target region. The motivation would be to avoid proximal sliding of the probe once it is latched onto the sheath. Castro discloses this rationale in col. 2:5-10 with regards to his obturator and cannula system.

Response to Arguments

Five independent claims now exist in the Application (32, 66, 73, 80, 87). Independent claim 32 is allowable for reasons presented, *infra*. The remaining independent claims are rejected above.

Claims 32-34, 36,39-41,44,46, and 65 are allowed because LeVeen neglects to disclose or suggest a cover **with a surface electrode**. (Claim 32 is independent. The remainder of the allowable claims depends from claim 32).

Independent claims 66 and 73 are rejected above. LeVeen discloses, *inter alia*, a cover (**the disc** at the proximal end of sheath 502) removably or selectably attachable to the probe (510) and adapted to span a region of tissue (S) over the target region (TR) and a connector (502) that removably or selectively attaches the cover (disc) to the probe (510) as depicted in figure 12. Castro is included in the rejection in order to better show a connector (22,47, figure 1) between an obturator (12; analogous to LeVeen 510) and a cannula (20; analogous to 502) capable of being removably and selectively attachable to each other. Although the LeVeen probe 510 is not an obturator as is Castro element 12, the intended use of the two analogous pieces is not relevant (this fact is irrelevant toward rejections the Applicant's system claims). What is important is the structure of Castro element 12 and its ability to connect with the cannula (20). The probe (510) and sheath (502) in LeVeen can be easily modified to include the connector mechanism (22,47) in Castro. The motivation would be to avoid proximal sliding of the probe (510), once it is latched onto the sheath (502). Castro discloses this in col. 2:5-10 with regards to his obturator and cannula system.

Independent claim 80 is rejected above. Assuming that the Applicant's dimensions of the disc/cover are optimal, the Examiner contends that the dimensions would have been determined through routine experimentation, thereby making obvious the limitation in claim 80, "a cover...adapted to span at least a region of tissue spanned by the deployed electrodes.

Art Unit: 3739

Independent claim 87 is rejected above. Castro discloses a member (22, see figure 3) with a cover (distal wall of member) that does not penetrate tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J Vrettakos whose telephone number is 703 605 0215. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on 703 308 0994. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746 7013 for regular communications and 703 746 7013 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0858.

Pete Vrettakos
January 29, 2004



MICHAEL PEFFLEY
PRIMARY EXAMINER